therapeutically effective dose of oxybutynin to provide an increased therapeutic index.

2. (Amended) The sustained release dosage form according to claim 1, wherein the plasma concentration is proportional to the sustained release dose.

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3. (Amended) The sustained release dosage form according to claim 1, wherein the sustained release dosage form releases up to 25 mg per hour of oxybutynin, or therapeutically acceptable oxybutynin salt thereof.

4. (Amended) The sustained release dosage form according to claim 1, wherein the sustained release dosage form comprises up to 650 mg of oxybutynin, or therapeutically acceptable oxybutynin salt thereof.

5. (Amended) A sustained release dosage form comprising oxybutynin and a pharmaceutically acceptable carrier for managing dry mouth associated with oxybutynin, wherein the sustained release dosage form upon once daily use is characterized by a sustained release therapeutically effective dose up to 25 mg per hour to provide an increased therapeutic index.

6. (Amended) Oxybutynin for use in providing a sustained release dosage form comprising oxybutynin and a pharmaceutically acceptable carrier, wherein the sustained release dosage form contains up to 650 mg of oxybutynin and up to 450 mg of a pharmaceutically acceptable carrier for releasing up to 25 mg per hour of oxybutynin to provide an increased therapeutic index.

7. (Amended) A method for managing dry-mouth in a patent administered oxybutynin, wherein the method comprises orally administering to the patient a sustained release dosage form comprising an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt thereof, that administers the oxybutynin at a controlled rate over twenty-four hours to provide an increased therapeutic index.

8. (Amended) A method for managing dry mouth in a patient administered oxybutynin for the management of incontinence, wherein the method comprises administering a sustained-release dose of 5 mg to 30 mg of a member selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt thereof up to twenty-four hours to provide an increased therapeutic index.

9. (Amended) A method for relaxing bladder muscles and for managing concomitantly dry mouth in a patient administered oxybutynin hydrochloride, wherein the method comprises administering 5 mg to 30 mg of oxybutynin hydrochloride in a sustained rate up to twenty-four hours to provide an increased therapeutic index.

10. (Amended) A method for decreasing the incidence of dry-mouth in a patient administered oxybutynin, wherein the method comprises orally administering to the patient a sustained-release dosage form comprising an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt thereof, that administers the oxybutynin in a controlled rate over twenty-four hours to provide an increased therapeutic index.

11. (Amended) A method for decreasing dry-mouth in a patient administered oxybutynin for the management of incontinence, wherein the method comprises administering a sustained-release dose of 5 mg to 30 mg of a member selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt thereof up to twenty-four hours to increase the therapeutic index.

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12. (Amended) A method for relaxing bladder muscles and for decreasing concomitantly dry-mouth in a patient administered oxybutynin hydrochloride, wherein the method comprises administering 5 mg to 30 mg of oxybutynin hydrochloride in a sustained-rate up to twenty-four hours to increase the therapeutic index.

13. (Cancelled)

14. (Amended) A method of manufacture of a sustained release dosage form indicated for oxybutynin therapy and for the management of dry mouth associated therewith, the manufacture comprising the step of incorporating oxybutynin into a sustained release dosage form, which when admitted daily into an environment of use releases oxybutynin to provide an increased therapeutic index.

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REMARKS

This amendment is filed in response to the Office Action dated September 11, 2001.

Claim 5 is objected to on the grounds that "an pharmaceutically" should read